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Abstract

Aim: To develop a pilot core competency framework for clinical research staff. Background: Clinical research networks in the United Kingdom (UK) are continuously developing as study demands change, thereby creating more diverse opportunities for individuals working in clinical research roles. It is imperative for clinical research staff to be skilled and competent to enable consistent delivery of high quality research studies and to provide the best care for participants, irrespective of their professional background. Method: A multi-method design was adopted which included three phases; Phase One – a conceptual review of current competency frameworks in the literature; Phase Two - a focus session with clinical researchers and thematic analysis to elicit suggestions and perspectives of core competencies; and Phase Three - development and refinement of a pilot competency tool. Results: Common indicators identified in the literature review were incorporated into the pilot competency framework. Three main overarching themes emerged from the thematic analysis of the focus session data; Theme One – clinical research attributes; Theme Two – career definition and development and; Theme Three – competency toolkit. Discussion: Current frameworks are comprehensive when applied to the research nurse role, however typically do not consider the competencies and development of non-registered staff. The present study also identified a gap in the consideration of soft skills as a core competency. Future work may include an additional phase to field test the pilot framework, seek feedback for further refinement and to include an assessment template. Conclusion: The establishment of a standardised competency framework for clinical research staff, irrespective of professional background, provides a valuable guide for individual researchers and their organisations. It adds to the evidence of the move towards professional registration for those working in clinical research and fosters motivation to develop and progress in the field.

Keywords	Competency, framework, continuing professional development, career, clinical research, researcher
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Research Data Related to this Submission

There are no linked research data sets for this submission. The following reason is given:
Data is submitted in the appendix under 'Data in Brief'. As a small pilot this forms the totality of the data.

Many thanks for taking the time to review our article manuscript and for providing comments on areas requiring clarification or improvement. We have taken into consideration your comments and would like to respond with the following remarks.

It is appreciated that the sample size of this study was small with an *n* of 4. As this was a pilot study of qualitative research we will use the data from this to guide further study design in which we would aim to gather a more diverse range of opinions. We have included comments around this in the discussion section, particularly focusing on involving a higher number of participants and also suggest improvements for methodology. We have also re-worded focus group to 'focus session' due to the small number of participants. Further detail of participant demographics has been presented in readable format as well as the independent researcher's qualifications expanded upon.

Participant protection has been described in further detail alongside the ethics process for doing this type of study within the NHS in the UK. Appendices now includes a list of the planned questions asked in the focus session. The text describing the themes found in the focus session has been expanded and presented in more readable format (tables provided). It is difficult to draw meaningful quantitative data from a small sample size, therefore we have not attributed quantitative data to participants' responses.

The literature review is now described as a conceptual review with further detail added regarding how relevant literature was obtained. Frameworks that were included were not limited to nursing e.g. the JTF (SOCRA have aligned with this working group) and TDR.

We have included some additional references from an updated literature search to support our rationale and our study findings.

We acknowledge that it is difficult to draw firm conclusions from a small sample size of the focus session. It is hoped that the additional phase of the conceptual literature review adds some weight to our framework. We would also like to highlight that this is a pilot framework and there would be plans for future research to develop and refine this to be implemented in UK research practice.

This pilot work was recently presented at the Research & Development Forum conference in Brighton, UK and received much positive feedback. We now have a number of potential sites who would like to be involved in trialling the wider roll out of this once the initial data is published.

Development of a core competency framework for clinical research staff

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Abstract

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Method: A multi-method design was adopted which included three phases; Phase One – a conceptual review of current competency frameworks in the literature; Phase Two - a focus session with clinical researchers and thematic analysis to elicit suggestions and perspectives of core competencies; and Phase Three - development and refinement of a pilot competency tool.

Results: Common indicators identified in the literature review were incorporated into the pilot competency framework. Three main overarching themes emerged from the thematic analysis of the focus session data; Theme One – clinical research attributes; Theme Two – career definition and development and; Theme Three – competency toolkit.

Discussion: Current frameworks are comprehensive when applied to the research nurse role, however typically do not consider the competencies and development of non-registered staff. The present study also identified a gap in the consideration of soft skills as a core competency. Future work may include an additional phase to field test the pilot framework, seek feedback for further refinement and to include an assessment template.

Conclusion: The establishment of a standardised competency framework for clinical research staff, irrespective of professional background, provides a valuable guide for individual researchers and their organisations. It adds to the evidence of the move towards professional registration for those working in clinical research and fosters motivation to develop and progress in the field.

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Introduction

Over the last decade, the United Kingdom (UK) has developed the most cohesive clinical research system in the world [1]. As the enterprise of clinical research expands, so too does the training and competence of staff involved throughout the study pathway. Several policies and guidelines are in place, including the Declaration of Helsinki and the EU Clinical Trials Directive [2], stating that research staff must have appropriate training and qualifications to undertake their tasks in clinical research [3]. Through the National Health Service (NHS) Constitution [4], the NHS is committed to conducting research to improve healthcare. Research is firmly embedded within 'The NHS Long Term Plan', with a described need for a skilled and competent workforce who can deliver high quality research, which in turn benefits the economy, patients and public health [5].

Recently, the National Institute for Health Research (NIHR) designed and published a national 'Integrated Workforce Framework' (IWF) to assist in describing the various roles and responsibilities in clinical research [6]. The IWF recognised that these roles are becoming increasingly diverse and more frequently included staff without professional registrations. The NIHR state that the IWF does not serve as a competency framework but is designed to be integrated with locally used frameworks to stand as an informative foundational resource. However, anecdotal experience has shown that it is uncommon for organisations to have competency tools readily available to use alongside a framework such as the IWF.

Defining standard competencies across clinical research roles is an emerging field and work to date has focused on the competencies of research nurses. The NIHR have observed that research teams and roles are transitioning to include more individuals who do not hold clinical or professional qualifications. For example, 50% of the cancer research network have different role remits other than a 'research nurse' [7]. Roles that were typically held by research nurses have also begun to be carried out by personnel from non-nursing backgrounds, which may be due to the growing concern of nursing shortages and vacancies in the NHS [8].

A recent study highlighted some of the challenges faced by clinical research practitioners (CRPs), who now comprise a large segment of research delivery teams in the NHS. Many CRPs describe a lack of available training that is specific to their roles [9]. They can also feel limited in utilising their clinical skills due to their non-registered position, which can have consequences on their professional development, morale and motivation. Although some training programs are available for research delivery staff in the NHS, they are not mandatory and it remains unclear how these map onto career progression or ensure staff are fully competent. As a result, career pathways, roles and responsibilities within research run the risk of being ill-defined, hence the need for a standardised competency framework for this cohort of research staff [10].

The objective of the present study was to develop a competency framework to pilot for NHS clinical research staff. This was achieved by a review of currently available frameworks and by collecting research staff perspectives of core competencies. A consistent definition of roles and responsibilities in research could potentially serve as a useful tool for those who choose to pursue a career in research. It has been recognised that there is currently a lack of well-validated research competency assessments in the literature [11]. A unified competency framework can also ensure that staff supervision and assessments are consistently measured against a standardised framework. Furthermore, if a research team work within a common structure this can facilitate cohesion, transparency and confidence across the interdisciplinary research team. We anticipate that a competency framework will support staff to be able to deliver high quality, ethically sound clinical research and that research volunteers are cared for by competent teams.

Method

The study design followed the concepts devised by While and Clark [12]. This used a multi-method design comprising of three main phases: Phase One, review of the literature; Phase Two, focus session; and Phase Three, development of the pilot competency tool.

Phase One, review of the literature

A conceptual review of the current literature was conducted to identify and group existing frameworks that have been developed in relation to clinical research competencies. These frameworks were

identified through database searching of PubMed and the Cochrane library. Additional frameworks were identified through the academic search engine Google Scholar. Key word searches included *competency*, *framework*, *continuing professional development*, *career*, *clinical research*, or *researcher*.

Articles or frameworks that were included in the conceptual review were analysed for common themes, categories or concepts. These commonalities were included in the current pilot competency framework in order to consolidate the current understanding of core competencies in clinical research.

Phase Two, focus session

A focus session was carried out with attendees whom the clinical research competency framework would directly apply to in future practice. The purpose of the focus session was to elicit suggestions and thoughts regarding how research staff view their roles, highlight the most valued competencies in the conduct of clinical research and reveal the current state of career progression within this field. The interview data posed as supplementary material to implement alongside the pilot framework developed after the literature review phase.

Table 1. Demographics of staff included in focus session semi-structured interview

Demographic	*n*
Age	
18-24	2
25-34	1
35-44	0
45-54	1
Gender	
Male	1
Female	3
Highest Education Level	
High school degree or equivalent	0
Bachelor's degree	2
Master's degree	3
Doctorate	0
Other	0
Years working in research	
0 – 1 year	0
1 year – 2 years	1
2 years – 3 years	2
3+ years	1

The focus session included staff from a Clinical Trials Facility (CTF) based in a mental health NHS Trust. The research staff represented varied clinical research roles at NHS Agenda for Change band 4 (n = 1) and 6 (n =3). All staff were interviewed together. An independent, external facilitator conducted the focus session in a semi-structured format where a pre-determined list of questions were asked but follow-up questions were also permissible (see Appendix 1). The focus session transcription data was examined utilising thematic analysis. The data was independently coded into themes by two non-medical researchers who each had over 5 years' experience working within clinical research settings. The transcript was examined to establish how current clinical research staff identify themselves within their roles, to determine how work performance is currently assessed in the workplace and to elicit any gaps or further support required within the field. Sub-themes were identified with supporting quotes, which then formed the overarching themes. The independent researchers analysed the transcription data separately then adjudicated and combined their data.

Phase Three, development of the pilot competency tool

A pilot competency tool was developed, informed by both the literature review and themes emerging from the focus session. The draft tool was reviewed by experienced (n=3) staff working in the field of clinical research, which included a research nurse (n=1), operations manager (n=1) and masters' level clinical studies officer (n=1). The National Competency Framework for Clinical Research Nurses [13] [14] served as a template for the current pilot competency tool but was adapted to fit the needs of an NHS clinical research facility.

Ethical considerations

Participants were informed that their participation was voluntary with a right to withdraw at any time. Full consent was obtained from each subject prior to engaging in the focus session. It was emphasised to the subjects, facilitator and transcriber that the focus session was strictly confidential. This was in order to respect the privacy of peers and maintain data and patient confidentiality. Ethics committee approval was not sought as this was considered an exploratory project for service development purposes within an NHS setting.

Results

Phase One – Literature review

The Oncology Nursing Society (ONS) recently developed a framework aimed towards nurses working in cancer clinical research [15]. Based on a review of current literature and a consolidation of experts in the oncology field, a set of key competencies were published in 2016. This framework is anticipated to support nurses who are new to oncology clinical trials. Such a framework addresses the potential complexity of working with specific populations and indeed, the competency framework also serves to help other organisations within their own specialities [16]. However, as it is specific to pre-registration student nurses, it can be interpreted as more of an induction framework. As such, it may lose value as nurses begin to embed themselves and choose to progress further in the field.

A National Competency Framework for Clinical Research Nurses is available to nurses working across research disciplines but also lends itself to adoption across a selection of research settings and roles that may identify with similar responsibilities to that of a research nurse [13] [14]. This is evidenced in another competency framework that was published and supported by the NIHR whereby various research networks within the UK collaborated and developed a competency framework for staff who may not routinely carry out clinical tasks in their research role [17]. Similarly, they noted that it would be necessary to adapt the framework to meet local needs of different clinical research sites around the UK. Both frameworks include an assessment template to enable staff to review and record their performance within each competence.

On a global scale, the Multi Regional Clinical Trials Centre (MRCT) integrated clinical trial competence by creating a 'harmonized competency framework' to outline the core competencies required for clinical research professionals who work at different stages of a clinical trials life cycle [18] [19] [20]. This framework provides a comprehensive overview of the main competency domains that would be required across all organisations involved in different types of clinical research. Similarly, The Special Programme for Research and Training in Tropical Diseases (TDR) created a single framework to be applicable across the full global health research team [21] [22]. The framework also uses a graded system to allow staff to recognise and develop their competencies and enable progression between roles.

A recent study identified 20 core competencies that made up a core competency index for clinical research professionals [23]. The Joint Task Force surveyed 238 research professionals using online survey software and asked respondents to indicate how competent they believed themselves to be on 51 identified clinical research competencies. The roles of respondents included clinical research coordinators, monitors, data managers, regulatory affairs staff and research administrators. The 20 core competencies that loaded onto the competency index could be separated into five domains; General, Medicines Developments, Ethics and Participant Safety, Data Management, and Research Concepts. The results of this study identified the breadth of competencies required by research teams

to deliver the life-course of a study. However the competencies are identified via self-selection methods and with participants who self-identified competencies they held rather than ones they needed. As such this paper may not reflect what the roles should do, but rather what the people in the roles are doing.

Most frameworks identified in the review have been comprehensive and pose as useful tools for many research sites. Flexibility and adaptability of a competency framework were valued. However, a lack of consideration of core clinical soft skills was identified, which is essential when working with any clinical population. These skills are invaluable to maintain participant retention and protection and to conduct high-quality studies, particularly if we are to witness a shift away from registered staff-led research centres. As such, common competencies across the frameworks identified above were amalgamated and a soft skill competency domain was to be included in the present pilot framework.

Phase Two – Focus Session

Three main overarching themes emerged from the thematic analysis of the transcript:

Theme One: Clinical research attributes

The participant's initial responses with regards to the skills required to work in clinical research gravitated toward soft-skills, with most highlighting the importance of having a positive relationship with volunteers. The concept of warmth and compassion were discussed by the group as important when interacting with research participants. The focus session attendees also used the word 'boundaries', which are important to develop and maintain in a researcher-participant relationship (Table 2). These clinical research attributes all clustered around topics that would be uncommon to see in training day agendas, where the focus is typically on practical and operational skill development.

Band 6: *"You need to be a people's person"*
Band 6: *"Compassion brings them in"*
Band 4: *"…giving people a warm, welcoming feeling"*
Band 6: *"Being able to keep boundaries"*

Table 2. Transcript data relating to soft-skills

All of the participants had non-clinical qualifications and came from non-medical backgrounds (psychology *n=3*; finance *n=1*). They all highlighted that their roles required the need to have certain knowledge and skills that were beyond their academic background. These included having some medical knowledge to understand the context of their role, as well as developing competencies in skills such as venepuncture and performing an electrocardiogram (ECG) recording. There was also discussion about certain roles being involved in the financial running of the unit, an area that would not typically have been covered in previous training, or as part of a researcher induction programme (Table 3).

Band 6: *"Some medical knowledge is also important"*
Band 6: *"We get to do a lot of things here. Our manager trains us to do a lot. Bloods, ECGs etc."*
Band 6: *"We all do finances as a part of our roles"*

Table 3. Transcript data relating to academic background

Several interpersonal communication skills also emerged as required attributes to fulfil their roles. The group acknowledged that being a clear communicator was important, and recognised that there was a diverse group of colleagues that a clinical researcher could interact with, including those from industry (Table 4).

Band 4: *"A good listener"*
Band 6: *"Good communication, clarity in what you say, keeping it simple"*
Band 4: *"…being welcoming, open"*
Band 6: *"…relationship… with pharmaceutical company, CRO, monitors"*

Table 4. Transcript data relating to communication skills

Theme Two: Career definition and development

The participants of the focus session comprised of both NHS Agenda for Change band 4 and 6 roles and there appeared to be some overlap in their duties. For instance, they all carry out testing and assessments of volunteers on different studies, manage some finances and work directly on study visits. Some of the participants also used clinical research titles interchangeably to define their role and there was often a lack a clarity around how the job roles should be described to people outside of the team. A lack of personal identity in the role was identified by one attendee, questioning when others asked what it was they did within their role. Job descriptions were discussed with the suggestion that these may not always reflect the daily tasks due to being written in a loose manner (Table 5).

Band 4: *"…a research assistant slash clinical data manager"*
Band 6: *"…a clinical research coordinator, or officer I think is the title"*
Band 6: *"It's odd when someone asks what your job is – you ask, what do I do?"*
Band 6: *"The job description is made quite loose, vague in a way"*

Table 5. Transcript data relating to definition of roles

One of the participants stated that there was a *"usual path"* that the staff take in terms of development, for example, you start as an assistant psychologist and develop to become a study coordinator. However, there was an overall consensus in that all participants stated that career development was not well-defined in their research roles and there was a feeling of being "*stuck*". There was a clear lack of a career development pathway for those in these roles (Table 6).

Band 6: *"We are quite niche, development-wise"*
Band 4: *"In a research avenue, it isn't clear cut, there isn't any guidance. You do a research post, coordinator post, or do a PhD but you don't know what it means to have one. No clear guidance"*
Band 6: *"I think the one thing we agreed on was that we weren't sure about where to go from here"*

Table 6. Transcript data relating to career development

Theme Three: Competency toolkit

The group harmonised on the thought that a competency framework would be a useful tool, however there were mixed views regarding how it should be structured. One participant expressed that a competency framework may be too concrete but another discussed that this would allow competencies to be assessed objectively. Flexibility and the ability to individually tailor a framework were discussed as important to some of the focus session attendees. The possibility of an assessment and objective measurement of competency and progress was attractive to some of the attendees (Table 7).

Band 4: *"…to have that structure would be quite nice"*
Band 6: *"As long as it's not too prescriptive. It might remove flexibility"*
Band 4: *"…having someone there to really assess you and to be objective about it is important"*
Band 4: *"Some people would prefer it to be prescriptive"*
There was also some consideration of staff competencies fluctuating, therefore flexibility within a competency framework would be highly valuable.
Band 6: *"It's very individual"*
Band 6: *"…if you don't do this often, you can fluctuate"*

Table 7. Transcript data relating to structure of competency framework

Phase Three - development of the pilot competency tool

Four main themes were included in the pilot competency framework, each of which were broken down into several competency domains: Background (three domains); Study Conduct (four domains); Data Management (three domains); and Professionalism (three domains). Each domain was paired with a competence statement that served as the central definition of what the competency governed. Each domain included examples of the main knowledge, skills and behaviours that comprise the competency. The competency was then broken down into examples of how it can be demonstrated across NHS Agenda for Change Bands 4-8 (see Appendix 2).

Discussion

Research networks in the UK have seen a substantial growth in the last decade due to recent investment of the UK government [24]. There has so far been great emphasis on clinical research sites being led by staff who hold clinical registrations, such as nurses. As research embeds into NHS services there is greater demand for competent research staff to deliver high quality studies and to ensure the safety of participants. These research staff are likely to come from an increasing spread of professional backgrounds, including, but no longer limited to, nursing. The current pilot competency framework incorporating staff from non-nursing backgrounds was developed for this reason.

The first phase of the study revealed very few competency frameworks relevant in the research arena. Of those that are available in the UK, it is noted that they are broad and mainly aimed at clinical research nurses [13] [14] [15] [16]. However, what was highly valued in these frameworks was the consideration that different research organisations work uniquely and that their single frameworks would need to be adapted to fit alternative specialities. The present literature review also analysed

competency frameworks that are globally available. The MRCT outlined core competencies that would be relevant across different research roles and also considered the competencies that would be required when working across different study designs [18]. Likewise, the TDR offers a framework that affords itself to being applicable to various team structures by defining different roles and how they fit into different study designs [21]. These frameworks provided the pillar for the pilot competency framework, that is, a structure that enables flexibility for different research sites to adopt according to their speciality and team dynamics.

Not only was the literature review useful in building the structure of the current framework but it also provided information regarding the specific competencies required of clinical researchers. The skills, behaviours and knowledge that were included in the cited frameworks are the essential building blocks to delivering high quality research. These competencies are valuable in that they are transferrable and can be adopted by diverse research teams, therefore it was important to implement these competencies into the current pilot framework.

Many of the existing competency frameworks have been comprehensive and useful in building the content of our pilot. However there appeared to be a gap in the consideration of soft skills that would be required in certain areas of clinical research. This is of particular significance when working with vulnerable populations, such as mental health, older adults and children. Many frameworks to date have been tailored for research nurses to utilise in highly medical fields. Soft skills are a vital component of working within any clinical environment, therefore must be an intrinsic competency of clinical researchers. If research sites are becoming increasingly comprised of staff without nursing registrations, it is imperative that they are equipped with not only the technical competencies, but also the soft skills to work sensitively with any clinical population.

In order to obtain supplementary data in relation to clinical research competencies, a focus session was conducted which involved various non-clinical research staff within an NHS clinical trials facility. The data collected from this second phase substantiated the importance of researchers requiring clinical soft skills in their roles. It is unsurprising that soft skills were the initial competencies discussed in the focus session, given that they worked with a vulnerable population (dementia and mental health). This provided further justification for the pilot framework to include soft skills as a competency domain in itself, which was seldom included in the frameworks identified in phase one.

Phase two also revealed that the current state of career development in clinical research is unclear. The clinical research profession is a growing enterprise and not only is it imperative for staff to be equipped with relevant competencies, but are also supported in continuing professional development. Although all members of the focus session attested to having regular supervision, the method of how these were structured or how their performance were measured was unclear. This is consistent with the findings of phase one which identified a dearth of competency frameworks that are readily available for research staff, particularly those specialising in certain areas that involve vulnerable populations.

Some views expressed by members of the focus session echoed that of the CRPs in Faulkner-Gurstein and colleagues' study [9]. For example, there was a great overlap of duties between band 4 and band 6 research staff in the focus session, similar to that described by the CRPs where they are expected to have clinical skills, provide admin support and data management across the research delivery pathway.

The small sample size of the focus session limited the amount of data that could be collected. Furthermore, the focus session was mixed with different research staff with varying level of expertise.

There was some overlap and similarities in their descriptions of clinical research roles. This made it challenging to disentangle under which pay grade or role a competency would fall under. Future developments of research competency frameworks would benefit from larger focus groups held at different clinical research sites comprised of staff of the same pay grade or role. The small sample size was partly due to staff availability. As such, the present study could have benefited from conducting individual interviews with more clinical research staff in order to obtain more prolific qualitative data.

The next step would be to conduct an additional phase that includes a field test of the pilot framework amongst different research sites to explore its suitability and acceptability for research staff. Selection of research sites should vary from small research teams, to services with high throughput of patient recruitment and staffing across different medical specialities. The pilot framework would be field tested for a minimum of one year with feedback collected from teams in both a focus group format and individual interviews. Once this feedback has been collected and analysed, the pilot framework will be revised in light of the findings. After revision, the competency framework should also follow suit with some of the cited frameworks from phase one, by including an assessment template. It was highlighted by some members of the focus session in phase two that workers' skills can fluctuate, therefore assessment of competencies should be a dynamic process with periodical reviews. This would enable research staff to utilise the framework as an objective measure of their competencies and identify development needs. Once a final competency framework is drafted, it would serve as a useful tool to complement other available resources, such as the IWF developed by the NIHR [6]. It is hoped that the establishment of a standardised competency framework for clinical research staff will pose as a valuable guide for researchers in how to deliver high-quality studies and foster motivation to develop and progress further in the field.

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Conflict of interest

None.

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Conflict of Interest and Authorship Conformation Form

Please check the following as appropriate:

☑ All authors have participated in (a) conception and design, or analysis and interpretation of the data; (b) drafting the article or revising it critically for important intellectual content; and (c) approval of the final version.

☑ This manuscript has not been submitted to, nor is under review at, another journal or other publishing venue.

☑ The authors have no affiliation with any organization with a direct or indirect financial interest in the subject matter discussed in the manuscript

- The following authors have affiliations with organizations with direct or indirect financial interest in the subject matter discussed in the manuscript:

Author's name	Affiliation
Authors have no conflict of interest or affiliations to declare.	

Appendix 1 – Focus session questions

1. What is your role and what are your main responsibilities?
2. What are the most important skills, knowledge and qualities needed to fulfil your role?
3. Are there certain aspects of your role that you did not expect when you first started?
4. How do you think your roles and responsibilities differ from other research staff at other clinical trial units?
5. Do you feel that career progression is clearly defined in your area of work?
6. How do you self-assess your skills or identify areas of development?
7. What are your first thoughts about competency tools and using this as a framework in your area of work?

Appendix 2 – Pilot Core Competency Framework for Clinical Research Staff

Theme	Competency Domain	Competence Statement
1. Background	A: Regulatory frameworks	Understands the historical and current political context and relevant policy governing clinical research in the UK
	B: Research design	Demonstrates an understanding of the design and development of different types of clinical research studies
	C: Ethical considerations	Understands the role and remit of research ethics committees in the UK
2. Study conduct	A: Operation of clinical research	Demonstrates an understanding and ability to discuss study-specific protocol requirements and implement strategies that contribute to the operation of clinical research
	B: Safety considerations	Incorporates and considers the care, safety and protection of human subjects in the conduct of clinical research
	C: Research administration	Awareness of research administration and demonstrates an ability to prioritise and manage administrative tasks between studies
	D: Study feasibility	Considers the feasibility of studies and demonstrates an understanding of how this contributes to site set-up
3. Data management	A: Confidentiality and data protection	Awareness and application of data protection and maintains participants confidentiality
	B: Data quality	Encompasses how data are acquired and demonstrates an ability to accurately capture, monitor and maintain data
	C: Data retention	Awareness and application of secure storage and archiving of data
4. Professionalism	A: Teamwork	Awareness of responsibilities of key personnel in clinical research and effectively collaborates with inter-professional teams
	B: Soft skills	Recognises the fundamentals of communication and effectively applies them to relevant stakeholders in clinical research
	C: Technical clinical skills	Encompasses physical health matters relative to population and aware of how to monitor these in clinical research

Theme 1 – Background to Clinical Research

1A: Understands the historical and current political context and relevant policy governing clinical research in the UK

Knowledge	Skills and Behaviours

• Principles of:
  - Declaration of Helsinki
  - Nuremburg Code
  - International Conference of Harmonisation Good Clinical Practice (ICH GCP)
• Relevant UK legislation:
  - Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) & Amendment Regulations 2006 (2006/1928)
  - Human Tissue Act
  - Mental Capacity Act
• Role of MHRA in the regulation of CTIMP and medical devices research
• Breaches in GCP; procedure when identified or suspected
• Political and strategic developments in clinical research
	• Attends and maintains GCP training as per policy
	• Applies principles of GCP in the conduct of clinical research
	• Identifies the relevant regulatory frameworks that govern clinical research conduct
	• Aware of own research network and their role in supporting the organisation
	• Understands the relevance of historical development of clinical research to current research and policy

Example of how competence is demonstrated:

Band 4	Band 5	Band 6	Band 7 & Band 8

• Attend GCP introduction course
• Identify how the principles of GCP are implemented
• Aware research is important to improve patient care
	• Discuss how principles of GCP are implemented
	• Recognises own limitations and completes relevant training
	• Awareness of studies within the team and wider speciality area
	• Discusses own contribution to delivering research
		• Comprehensive understanding of the regulatory and legal frameworks related to the conduct of clinical research
		• Supportive in the training and development of others within the team
		• Discusses studies within the team and wider speciality area
			• Demonstrates leadership by:
			  - Ensuring processes, policies and standard operating procedures (SOPs) are in place
			  - Championing the role of clinical research in the development of health and social care
			  - Providing comprehensive information regarding strategic developments that influence clinical research

Theme 1 – Background to Clinical Research

1B: Demonstrates an understanding of the design and development of different types of clinical research studies

Knowledge	Skills and Behaviours

• Research study design:
  - Protocol design
  - Sample size and power
  - Inclusion and exclusion criteria
  - Randomization
  - Blinding and unblinding
• Clinical research set-up and process within the team and organisation
• Role and relevance of patient and public involvement in all stages of the research process
• CTIMP studies; pharmaceutical industry sponsored clinical trials – drug discovery process and licensing of medicines in the UK
• Multi-centre studies
• Elements of clinical and translational study design
	• Identifies the research design and methodology used for trials/studies within the research team
	• Seeks to understand the relevance of the design and methodology to their role and the wider research team
	• Describes design of current clinical research studies running within the team and wider speciality area
	• Communicate study design and set-up to relevant stakeholders

Example of how competence is demonstrated:

Band 4	Band 5	Band 6	Band 7 & Band 8
• Degree level understanding of research study design • Aware of design of studies currently working on	• Describes design of current studies within research team and communicates this to wider audience	• Involvement in designing studies • Understanding of variety of study designs	• Supports design of new studies • Advises on design of studies

Theme 1 – Background to Clinical Research

1C: Understands the role and remit of research ethics committees in the UK

Knowledge	Skills and Behaviours
• Role and responsibilities of National Research Ethics Service (NRES) and structure of Research Ethics Committees (RECs) • Role and responsibilities of the R&D departments • Local policy and procedure related to ethical review and research governance • Regulatory requirements for protocol amendments and closure of a trial • Indemnity, financial and contractual agreements • Regulatory reporting procedures when protocol is breached • Current and historical ethical principles	• Recognises the need to ensure that appropriate ethical opinion and governance approvals are obtained before any research activities are undertaken • Assist with the acquisition, distribution and tracking of relevant trial documentation for study set-up • Articulates understanding of regulatory requirements • Undertakes relevant educational activities/training • Works and complies to ethical standards and regulatory requirements

Example of how competence is demonstrated:

Band 4	Band 5	Band 6	Band 7 & Band 8
• Complies with ethical standards • Aware of how to raise concerns when protocol is breached	• Has knowledge of RECs and R&D departments and its function • Takes part in relevant educational activities • Identify the regulatory permissions that have been obtained for the studies currently working on	• Discusses topic and issues relating to research ethics and governance • Familiar with regulatory requirements	• Provides knowledge and guidance around research ethics • Ensures staff are working within regulatory requirements during research activities

Theme 2 – Study Conduct

2A: Demonstrates an understanding and ability to discuss study-specific protocol requirements and implement strategies that contribute to the operation of clinical research

Knowledge	Skills and Behaviours

• Protocol of studies currently working on:
  - Extracting relevant information
  - Schedule of events
  - Eligibility requirements
• Equity of access for participation in research/Informed consent
• Participant pathway planning
• Participant recruitment
• Appropriate control, storage and dispensing of investigational products
• Ordering couriers
• Rationale behind adherence to ethically approved study protocols
• Randomisation
• Standard Operating Procedures (SOPs)
	• Verify eligibility criteria and collects relevant information for participant recruitment
	• Registers participants according to protocol requirements
	• Adheres to schedule of events and plans study/follow-up visits
	• Develops checklists, worksheets, screening tools and SOPs
	• Arrange couriering and safe handling of samples (Including IATA training as necessary)
	• Appropriate use of PIS and ICF
	• Complies with GCP guidelines

Example of how competence is demonstrated:

Band 4	Band 5	Band 6	Band 7 & Band 8
• Explain studies currently being run within research team • Awareness of eligibility criteria and screens/recruits participants according to protocol • Attends relevant training • Communicates study pathway to volunteers and distributes PIS appropriately	• Communicates with internal and external agencies to assess eligibility • Develops checklists, SOPs etc. to support adherence to protocol • Monitors state of recruitment and submits recruitment logs/figures to appropriate agencies	• Plan pathway for participant and identifies any challenges • Encompass study management and co-ordination • Discuss protocol requirements and guides research staff accordingly • Familiarity with the on-going process of informed consent	• Contributes to and encourages training of research team with a view of developing colleagues and enhance best practice in the delivery of clinical research • Promotes recruitment strategies • Networks across clinical departments

Theme 2 – Study Conduct

2B: Incorporates and considers the care, safety and protection of human subjects in the conduct of clinical research

Knowledge	Skills and Behaviours

• Adverse Events (AEs); Serious Adverse Events (SAEs); Suspected Unexpected Serious Adverse Reaction (SUSAR):
  - Differentiate the types that can occur in clinical trials
  - Safety reporting measures and procedure
  - Identification process
• Methods by which safety issues are identified and managed in clinical research
• Pharmacovigilance
• Licensing authorities and licensing of investigational products
• Awareness of issues that may be involved when dealing with vulnerable participants
• Local safeguarding policies for vulnerable populations
• Risk assessment and management
• Local Medicines Policy
	• Compliance with approved reporting procedures in the event of a safety issue
	• Sound clinical judgement and ability to risk assess
	• Calculates balance of risk with participant benefit
	• Compare and contrast clinical care and management of research participants
	• Raises any concern that may threaten wellbeing of participant
	• Demonstrates safe and effective care of patients and/or participants in research

Example of how competence is demonstrated:

Band 4	Band 5	Band 6	Band 7 & Band 8
• Attends relevant training • Reports or raises any concerns that arise during research activities with patients or participants • Communicates appreciation of research participation to volunteers	• Sensitively communicates potential risks (e.g. side effects) involved in clinical trials to volunteers • Ability to risk assess when dealing with vulnerable populations within or outside the research environment	• Knowledge and identification of adverse events that can occur in research • Describes and discusses the reporting requirements when safety issues arise	• Recommends and guides safety measures for colleagues to take in the conduct on clinical research • Apply management concepts and effective training methods to manage risk and improve quality

Theme 2 – Study Conduct

2C: Awareness of research administration and demonstrates an ability to prioritise and manage administrative tasks between studies

Knowledge	Skills and Behaviours
• In house and sponsor documentation systems • Acquisition of clinical records and systems used to retrieve these • Safe and appropriate storage and/or discard of confidential records/information • Research literacy	• Communicates through different media • Prioritises and organises well between tasks • Proficient in IT • Manage telephone enquiries • Maintains accurate documentation • Ordering and maintaining study supplies

Example of how competence is demonstrated:

Band 4	Band 5	Band 6	Band 7 & Band 8
• Manages telephone enquiries in relation to studies working on • Organises and submits research documentation appropriately	• Collects relevant clinical records appropriately • Ensure research supplies are stocked and up to date	• Ensure accurate documentation of research activities are completed • Manages study supplies and ensures adequate resources are available for research conduct	• Manages research team and delegates administrative duties • Identifies resource or financial constraints

Theme 2 – Study Conduct

2D: Considers the feasibility of studies and demonstrates an understanding of how this contributes to site set-up

Knowledge	Skills and Behaviours
• Requirements to conduct research within the sites currently placed in • Site Initiation Visits (SIV) • Overall site preparation and planning • Participant recruitment • Pathway planning • Risk assessment and feasibility • Funding sources, budget and resource requirements	• Recognises importance of planning prior to study opening • Contributes to overall preparation of site • Identifies opportunities to contribute to feasibility assessments: - Sources of recruitment - Identify patients to pre-screen - Database set up and searches - Attend MDT meetings • Liaise with R&D and other support services to set up meetings

Example of how competence is demonstrated:

Band 4	Band 5	Band 6	Band 7 & Band 8
• Attend relevant meetings to recognise planning procedures • Aware of participant groups required for study and works within potential sources of recruitment • Assist with set up of site files compliant with research governance and GCP	• Assist with acquisition, distribution and tracking of study set up resources • Participate in feasibility assessments • Develops and prepares documents and facilities for study visits	• Co-ordinates plan for study set up • Identify relevant training for research team involved • Plan study schedules • Complete feasibility questionnaires • Financing for studies responsible for	• Undertakes and oversees risk and feasibility assessments • Acts as a knowledgeable source for research team involved in the site set up for a new study • Liaise with sponsor representatives • Negotiate contracts with external companies

Theme 3 – Data Management

3A: Awareness and application of data protection and maintains participants confidentiality

Knowledge	Skills and Behaviours
• Local and national policies and procedures relating to data collection, storing and secure transfer: - Data Protection Act 1998 - Confidentiality Code of Practice - Caldicott report & local Caldicott guardian - Freedom of Information Act 2000 - Local information governance policy • Maintain confidentiality of participants involved in research • Actions required when data protection processes are not adhered to - Fraud and misconduct • Potential obligation to disclose confidential and sensitive information • Informed consent process	• Respects participants confidentiality and ensures it is maintained • Applies the principles of data protection and contributes to the safe storage and retention of data • Raises concern about poor data protection • Anonymises data correctly • Communicates to participants the purpose of collecting their data and assures confidentiality • Care and safety of patient data

Example of how competence is demonstrated:

Band 4	Band 5	Band 6	Band 7 & Band 8
• Aware of own role in maintaining confidentiality of participants and protecting data • Attends relevant training in relation to data protection	• Identifies the measures in place to ensure data protection and confidentiality • Raises concern if data protection is not adhered to	• Consistently adheres to the requirements to protect confidentiality and data • Leads by example of securing sensitive and confidential information	• Develops procedures to enable data protection • Ensures the research team operates according to local and national policies relating to data protection and confidentiality

Theme 3 – Data Management

3B: Encompasses how data are acquired and demonstrates an ability to accurately capture, monitor and maintain data

Knowledge	Skills and Behaviours
• Local and sponsor procedures to monitor, audit and track study data • Data queries and resolution • Study protocol • Standard Operating Procedures (SOPs) • Data entry techniques • Local and national policies relating to data collection and safe transfer • Scoring of data according to study protocol • Aware of importance of collecting high quality data and its relation to the research question • Quality assurance • Data accuracy and integrity	• Check and resolve data queries in a timely manner • Recognises the importance of accurate and comprehensive documentation and data collection • Identifies and manage inconsistencies in data or Case Report Forms (CRFs) • Encompasses how data are acquired and managed in research • Ensures data quality through accurate data capture and CRF completion • Adheres to the roles and responsibility of documentation • Project management • Translate data into knowledge

Example of how competence is demonstrated:

Band 4	Band 5	Band 6	Band 7 & Band 8
• Evidence of accurate and timely data entry • Captures and scores data correctly • Liaise with research team to complete data collection • Utilise paper and computer based data entry systems	• Responds and resolves data queries • Collects and reports local recruitment data • Develops and prepares documents for data collection • Identify key components of SOPs relevant to role	• Manages and overlooks data in CRFs to ensure adherence to protocol • Contributes to auditing and monitoring of research study data • Develops SOPs • Ensure data quality and manages queries	• Manages and supervises accurate data completion • Seeks to reduce data queries • Ensures local policies and SOPs are adhered to by the research team

Theme 3 – Data Management

3C: Awareness and application of secure storage and archiving of data

Knowledge	Skills and Behaviours
• Filing systems • Site Master Files / Essential Documents • Storage of site files, CRFs, investigator brochure, protocols • Storage of data • Archiving of data following study closure	• Ensure secure filing and storage of study documentation in accordance with research governance requirements • Recognises the importance of maintaining secure storage and retention of data • Practices good record keeping

Example of how competence is demonstrated:

Band 4	Band 5	Band 6	Band 7 & Band 8
• Contributes to safe and secure storage of research data	• Consistently applies principles of secure storage of data/documentation	• Contribute to study closure and archival preparation • Organises how data is securely stored and filed • Maintain and update essential documents in the site file	• Advises research team on safe data storage • Manages incidents of poor data storage

Theme 4 – Professionalism

4A: Awareness of responsibilities of key personnel in clinical research and effectively collaborates with inter-professional teams

Knowledge	Skills and Behaviours
• Responsibilities and roles of key personnel involved in research • Practices of leadership • Purpose and function of the research team • External agencies or stakeholders in research • Delegation logs • Equality and diversity within teams	• Creates positive working relationships • Contributes to team building • Contributes and encourages development of colleagues within the research team • Collaborative decision making • Organises study pathway and visits with research team

Example of how competence is demonstrated:

Band 4	Band 5	Band 6	Band 7 & Band 8
• Consistently works within own roles and responsibility whilst seeking advice and support as appropriate	• Works efficiently with inter-professional teams and external agencies • Presents complex cases with wider team to determine appropriate course of action for volunteers	• Delegates research activities appropriately and maintains logs • Attendance of leadership and management courses • Co-ordinates study duties with wider team and other professionals	• Collaborates with research team to make decisions • Ensures and encourages development of staff • Applies principles of management to lead research team to conduct research efficiently and ethically • Management of team skill-mix

Theme 4 – Professionalism

4B: Recognises the fundamentals of communication, importance of engagement, and effectively applies them to relevant stakeholders and diverse subjects in clinical research

Knowledge	Skills and Behaviours
• Interplay between culture, environment and communication • Methods of conveying information to volunteers, other research bodies, Sponsor etc. • How personal communication style can affect clients • Principles of client engagement • Non-verbal communication • Cultural sensitivity • Public and Patient Involvement and Engagement (PPIE) strategies • Specific population needs	• Establishes and maintains relationships with volunteers, patients, clients and other professionals/agencies • Modifies communication in line with audience's level of understanding • Accurately hands over relevant information within research team • Actively listens and takes personal responsibility • Takes a proactive and personal approach to interpersonal relations • Creative, adaptive and focused approached to problem solving • Compassionate and sensitive of specific client group and carers • Emotional intelligence • Patient experience listening • Writing for publication and advertising

Example of how competence is demonstrated:

Band 4	Band 5	Band 6	Band 7 & Band 8
• Establishes and maintains communication with volunteers during initial recruitment period • Clearly conveys study information to volunteers and other colleagues	• Clearly presents relevance of research and study findings to colleagues • Communicates and hands over accurate information within research team	• Conveys accurate and up-to-date information to relevant bodies relating to studies working on • Appropriately communicates research activities to colleagues	• Encourages collaboration with clinical teams and other communities • Facilitates team building and development of communication within research team

Theme 4 – Professionalism

4C: Encompasses physical health matters relative to population and aware of how to monitor these in clinical research

Knowledge	Skills and Behaviours
• Physical health/medical issues relating to population being studied • Signs and symptoms of co-morbid physical health issues • Rationale for monitoring physical health • Infection control policy • Human Tissue Act • Informed consent process • Interaction between IMP, prescribed medication and physical health	• Measures, documents and interprets physical signs and symptoms • Performs routine diagnostic tests according to study protocol • Acts appropriately with sudden changes or abnormal results in participant's health • Safely performs physical health monitoring • Ensures patient comfort during physical health monitoring • Correctly prepares and labels samples for shipping • Safe and aseptic venepuncture technique • Tracks laboratory results

Example of how competence is demonstrated:

Band 4	Band 5	Band 6	Band 7 & Band 8
• Attends all relevant physical health training • Adheres to policies relating to monitoring physical health, infection control • Knowledge of basic physical health issues and how to identify this	• Able to identify and reports any abnormal or sudden change in participant health • Obtains relevant medical records • Develops and prepares relevant documents to monitor physical health in line with study protocol • Duty of care in relation to equipment and resources	• Advance preparation for blood, urine, and other bodily fluid and tissue sampling of participants • Correctly labels and ships participant samples • Maintains contact with medical monitor	• Ensures training related to physical health is up to date within research team